REMARKS

The official action of 3 November 2009 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claim 1 has been amended more clearly to distinguish over the cited art through use of the "consisting of" transitional to exclude any element not recited in the claim. See MPEP 2111.03 and discussion below. Claim 1 has also been amended to recite that the claimed capsule can optionally include a health-enhancing component or a food additive or both in accordance with the description in the specification as filed at page 5, lines 11-15, and original claim 20 (now cancelled).

New claim 22 has been added more completely to define the subject matter which Applicants regard as their invention. Claim 22 incorporates product-by-process limitations further to define the capsule by the manner in which it is produced. As provided in MPEP 2113, and as discussed below, the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art where, as here, the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. The process limitations in claim 22 draw support from the specification as filed at, for example, Examples 1 and 2 on pages 7-8 and from US Patent 5,472,648, which is incorporated into the application by reference at page 6, lines14-16. The '648 patent describes the process limitations, including dropletizing of the droplets, maintaining for a residence time and the surface-hardening thereof at, for example,

column 5, lines 3-21 and claim 1.

Claims 9 and 10 have been amended to change their dependencies so that each of the claims now further limits the claim from which it depends thereby to remove the basis for the objections to these claims at page 2 of the official action.

The claims stand rejected under 35 USC 102(b) as allegedly being anticipated by Sekigawa et al or under 35 USC 103(a) as allegedly being unpatentable over Sekigawa et al in view of Hashimoto et al or over this combination of references further in view of one or more of Cardinal et al, Frechet et al and Bailly et al. The claims also stand rejected under 35 USC 102(e) as allegedly being anticipated by Kudo et al or under 35 USC 103(a) as allegedly being unpatentable over Kudo et al, either alone or in view of Bolton et al. Applicants respectfully traverse these rejections.

Sekigawa *et al.* disclose a coated solid medicament form comprising two or three successive coating layers, each formed from a specified coating material, of which the topmost coating layer is formed from cellulose ether, and the layer below the topmost coating layer is formed from chitosan (see column 2, lines 46-56). As described in Sekigawa, the multiple coating layers are needed in order to carry out the express purpose of the reference, namely to effect selective release of a medicament in the large intestine (see, e.g., Abstract and column 3, lines 9-24).

In contrast, by virtue of the "consisting of" transitional in the claims, the

claimed invention excludes a topmost coating layer of cellulose ether and any other element, step or ingredient not specified in the claim (see MPEP 2111.03).

Accordingly, and since the components of the chitosan embedded or encapsulate capsule of the claimed invention cannot contain a topmost coating layer as required by the reference, the chitosan embedded or encapsulate capsule of the claimed invention cannot be anticipated by Sekigawa *et al.* Moreover, since Sekigawa teaches that the additional coating layer(s) are needed for achieving the purpose of the capsules described therein, there could not have been any motivation or reason to modify the reference as would be required to arrive at the claimed invention. See MPEP 2143.01(V) ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."); see, also, MPEP 2143.05(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious."). Accordingly, Applicants respectfully submit that the Sekigawa cannot be used, either alone or in combination with any of the other cited references, to set forth even a *prima facie* case of obviousness for the invention as now claimed.

With particular respect to claim 22, the same is additionally patentable insofar as the process limitations in claim 22 limit **the structure** of the claimed capsule to one that is hardened on the surface only. In contrast, the object of Sekigawa et al is to form a coated **solid** medicament (see, e.g., Abstract and column 1, lines 55-62). In view of this object, there

could have been no motivation or reason to modify Sekigawa's capsules to arrive at the capsule defined by claim 22, which is surface hardened only at the surface.

Kudo *et al.* disclose an oral-uptake system which comprises a capsule formed with a compound <A> having a molecular weight of 1,000 or less and having a disulfide bond and a polymer <B> (e.g., chitosan). The compound <A> is decomposed into lower molecular compounds as a result of cleavage of the disulfide bonds due to reduction by enterobacteria so that improvement of water-solubility and/or acidity of the decomposition product is higher than the compound <A> (see column 5, lines 63-67). As with the case of the Sekigawa reference, the "consisting of" transitional of the claims excludes a coating layer formed by the compound <A> required by the reference. Since the claims exclude the compound <A> required by Kudo *et al.*, the claimed chitosan embedded or encapsulate capsule cannot be anticipated by Kudo *et al.* Moreover, since there could have been no motivation or reason to modify the reference to exclude the compound <A>, which the reference teaches as essential, the claimed invention cannot be rendered obvious by Kudo et al or any combination of references based thereon.

With particular respect to claim 22, the claim is additionally patentable because the process of formation excludes the water insoluble polymers which Kudo et al teach are needed to prevent leakage of drugs having high water solubility (see Kudo at column 8, lines 16-24). Moreover, claim 22 defines a capsule that is hardened on the surface only and this is also not taught in Kudo.

In view of the above, Applicants respectfully submit that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

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Respectfully submitted,

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